REMARKS

Claims 1-8 and 10-26 are pending in the present application.

Claims 1-7 and 10-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,355,401 to Graves et al. in view of either U.S. Patent No. 5,421,955 to Lau et al. or in view of U.S. Patent No. 5,902,475 to Trozera et al. Claims 8 and 13-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,355,401 to Graves et al. in view of either U.S. Patent No. 5,421,955 to Lau et al. or in view of U.S. Patent No. 5,902,475 to Trozera et al., and further in view of U.S. Patent No. 6,763,132 to Freifeld.

The Claims as Previously Amended are Patentable Over Graves in View of Lau or Trozera

Claims 1-7 and 10-12 were rejected under 35 U.S.C. § 103(a) as obvious over U. S. Patent No. 6,355,401 to Graves et al. in view of U.S. Patent No. 5,421,955 to Lau et al or in view of U.S. Patent No. 5,902,475 to Trozera et al. Independent claim 1 (from which rejected claims 2-7 and 10-12 depend) was previously amended in the Response to August 30, 2005, Office Action to recite the step of "determining an amount of therapeutic coating on the medical device" ... "wherein the selected portion of the coating to be removed is a portion of the coating sufficient to reduce the amount of coating on the medical device to a target amount of coating." Without addressing the propriety of combining these references, the Applicants argued then and continue to argue that none of the references disclose or suggest these previously-amended claim limitations.

Specifically, Applicants argued that these limitations provide for a target amount of therapeutic coating on a medical device to limit the amount of therapeutic dosage in the coating to be delivered to a patient by first determining the amount of therapeutic coating through

weighing, or calculating the weight of, the coated medical device to determine the portion of coating to be removed to achieve the targeted amount. *See* Specification, ¶¶ 0033-0035.

The invention in Graves generally regards removing electrically insulative coating from a cardiac pacemaker in a specific area to form a "window" to direct an electrical pulse to targeted tissue (e.g., myocardial tissue in the heart) and avoid stimulating non-targeted areas (e.g., surrounding pectoral muscle) by leaving insulative coating in those areas. See Graves, col. 1:40-65. Graves does not disclose or suggest the step of determining an amount of therapeutic coating to be removed by weighing the coating to calculate a remaining target amount of therapeutic coating for limiting dosage delivery.

In the Final Office Action, the Examiner referenced only the following sentence in the Abstract in Graves: "removing electrically insulative coating material from a portion of the titanium housing." The Examiner reads this sentence as supporting the notion that "[s]ome idea in a determining of an amount is inherent in the 'removing ... from a portion.'" *See* Office Action of February 7, 2006, at 4. The Examiner further concludes that "[i]dentifying the portion as a 'target amount' is not different from having an 'idea of which portion [from the housing in Graves] is to be removed.'" *Id.* Thus, the Examiner is apparently asserting that "some idea" of determining an amount of therapeutic would be inherent to the removal of electrically insulative coating in Graves. And, further, the Examiner is equating the removal of insulative coating from a portion of the titanium housing to create the "windows" of Graves as tantamount to the calculated removal of coating to leave a target amount for proper therapeutic dosing.

Applicants respectfully disagree. First, Applicants respectfully point out that the citation to the Abstract in Graves discloses the removal of the insulative coating material from a portion of the housing to form a "window" to direct an electrical pulse to targeted tissue. Graves does

not determine an amount of therapeutic coating in reducing the coating to a targeted amount to control dosage of the therapeutic coating. Because the insulative coating in Graves insulates and protects the tissue adjacent the coated housing from electrical stimulation regardless of how much insulative coating exists at that specific location, there is no need in Graves to determine the amount of coating in reducing the coating to a target amount, as disclosed in the cited passage in the Abstract.

Second, Applicants respectfully assert that the Examiner has not supplied any "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the applied art." M.P.E.P. § 2112, IV (emphasis in original). To the extent that the Examiner may be relying on the doctrine of inherency, Applicants respectfully point out that "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted); *see also Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic.

Here, it has not been shown that the step of "determining an amount of therapeutic coating" would necessarily flow from "removing electrically insulative coating material from a portion of the titanium housing" to create the "windows" in Graves. Removal of insulative coating in Graves to allow electrical stimulation does not require a determining step of the

amount of coating. Accordingly, the determining step does not necessarily flow from the recited passage in Graves. Moreover, the fact that the determining step may occur is not sufficient to show inherency. Inherency may not be established by probabilities or possibilities. *In re Robertson*, 169 F.3d at 745. Furthermore, "Some idea in a determining of an amount," by definition, cannot establish that the inherent "determining" step necessarily flows from the teachings of the applied art. *See* M.P.E.P. § 2112. Applicants respectfully maintain that the doctrine of inherency cannot supply the missing "determining" step.

Likewise, the devices in Lau and Trozera, which generally regard removal of an etchant-resistive coating mask to expose surfaces of a medical device prior to a chemical etching process for removal of substrate material (*see* Lau, col. 3:17-27; Trozera, col. 3:1-34), do not disclose the steps of determining an amount of therapeutic coating to be removed, and then removing coating to achieve a target amount of therapeutic coating to limit therapeutic dosage delivered to a patient. Thus, the applicants submit that claims 1-7 and 10-12 are patentable over both references, as well as Graves, alone or in combination.

The Claims are Patentable Over Graves in View of Lau or Trozera, and Freifeld

Claims 8 and 13-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,355,401 to Graves et al. in view of either U.S. Patent No. 5,421,955 to Lau et al. or in view of U.S. Patent No. 5,902,475 to Trozera et al., and further in view of U.S. Patent No. 6,763,132 to Freifeld. Independent claims 8 and 13 were previously amended to recite the step of "positioning at least one stent strut relative to the laser based on output from the pattern recognition system," in claim 8; and the limitation of "wherein the pattern recognition system identifies the position of at least one strut of a medical device relative to the laser, determines

whether the strut is in a desired position relative to the laser, and provides output to correct positioning of the strut relative to the laser," in claim 13. The Applicants assert that none of the references, including the newly-cited Freifeld reference, disclose or suggest at least the above limitations.

Neither Graves nor Lau discloses or suggests a system that identifies mis-positioned struts based on output, let alone provide corrections to controllers to alter stent positioning relative to a laser based on output for mis-positioned stents. *See generally,* Graves, col. 7:2-36; Lau, col. 7:3-14. Trozera does not even teach or suggest laser ablation, *see* Trozera, col. 2:34-35, let alone output from a pattern recognition system for identifying mis-positioned stents relative to a laser.

Newly-cited reference Freifeld also fails to "position[] at least one stent strut relative to the laser based on output from the pattern recognition system." Freifeld generally discloses a linear array electronic camera that creates an electronic line-by-line image of the stent for determining "the conformance of the tube to known dimensional tolerances or analyz[ing] the image for cosmetic or functional defects." *See* Freifeld, Abstract; col. 3:39-41. In other words, Freifeld checks for dimensional tolerances (*e.g.,* strut or wall thickness, surface waviness) against a model pattern. Freifeld does not re-position stents that have been mis-positioned relative to the laser based on any output to ensure accurate ablation, nor does Freifeld provide corrections to the controllers to alter stent positioning relative to a laser. The pattern recognition system in Freifeld merely supplies an "anchor pattern" against which the image of the tube is compared in determining cosmetic and tolerance differences. *Id.*, col. 3:51-54. Further, to the extent Freifeld "positions" any stent for comparing its dimensional tolerances, it "positions" the stent image against a model stent pattern, and not relative to a laser based on output, as claimed

in claim 8. And it certainly does not "correct positioning of the strut", whether relative to the anchor pattern or the laser, as claimed in claim 13.

In addition, there is no suggestion or motivation to modify the primary reference of Graves—which involves ablation to create electrically-conductive "windows" for generally round, strut-less pacemakers—with the pattern recognition feature of Freifeld to identify and position "strut position relative to a laser." One of ordinary skill in the art would not look to Freifeld, which discloses a dimensional tolerance checking system, to supply the missing system of altering strut positioning relative to a laser based on corrective output. Moreover, none of the cited references address the problem of correcting strut positioning relative to the laser for accurate ablation.

Thus, the applicants submit that claims 8 and 13-26 are patentable over the references either alone or in combination.

CONCLUSION

In view of the preceding remarks, the Applicant respectfully asserts that each of the pending claims are in condition for allowance and, therefore, requests reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Kenyon & Kenyon LLP Deposit Account No. 11-0600 for any applicable fee.

Should the Examiner require any additional information regarding this Response, the Examiner is invited to contact the undersigned at (202) 220-4200.

Respectfully submitted,

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